Docket Number: ENP-036

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Or et al.
Serial No. : 10/007,235
Filed : October 22, 2001
Title : Alpha-Hydroxyarylbutanamine Inhibitors of Aspartyl Protease

Art Unit : 1626
Examiner : Rebecca L. Anderson

#79

1/21/03

CERTIFICATION OF MAILING BY FIRST CLASS MAIL

Date of Deposit: **December 30, 2002**

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, BOX Non-Fee Amendments, Washington, D.C. 20231.

Stacie Capotosto

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RESPONSE TO REQUIREMENT FOR RESTRICTION AND REQUIREMENT FOR ELECTION OF SPECIES

Madam:

This paper is in response to the Office action faxed December 3, 2002 in the above-identified application for Letters Patent.

1. The examiner has made a requirement for restriction between three groups of claims as follows:

I. Claims 1-18 and 23 drawn to products of the formulas found in claim 1 on page 100, variously classified.

II. Claims 19-22 drawn to various methods of use of the compounds of claim 1, variously classified.

III. Claim 24 drawn to a pharmaceutical composition comprising the compounds of claim 1 and additional antiviral agent(s), variously classified.

Applicants request reconsideration of the requirement for restriction. The three sets of claims, as grouped by the examiner, recite subject matter which is so closely related as to warrant examination of all of the claims in the application.

Restriction between claims of different statutory categories present in one application is not mandatory but rather is within the discretion of the United States Patent and Trademark Office ("USPTO"). The statutory authority for restriction practice, 35 USC §121, states that restriction between two or more independent and distinct inventions claimed in one application may (emphasis added) be required and further provides that the validity of a patent may not be questioned for failure to require the application to be restricted to one invention.

Here, all the claims in the application could be examined conveniently in one application since the compounds and compositions recited in the Group I claims are recited in the Group II claims in the context of a method of treating or preventing a protease-precipitated disease, which is the utility taught in the application for the compounds and compositions. Thus, the subject matter of the respective groups of claims is so closely related that the sound exercise of discretion dictates the examination of all the claims in the present application.

In the alternative, the claim drawn to a pharmaceutical composition contained within Group III could be examined in conjunction with claim 23, which has been included within Group I by the Examiner. Thus, the combination of the subject matter of Groups I and III for examination is respectfully requested.

Nevertheless, should the USPTO continue to assert the restriction requirement, applicants provisionally select the claims of Group I (1-18 and 23) for examination without prejudice to their right, pursuant to 35 U.S.C. §121, to file divisional applications to the non-elected claims of Group II (19-22) and Group III (24).

2. The examiner has also required applicants to elect a single disclosed species for examination.

In compliance with this requirement, applicants hereby elect compound EP 001237 (See Table 1, page 32). The claims readable on this single elected species are claims 1, 7-8, 11-14, and 16-18.

It is also noted that the examiner has also stated:

"Upon election of a single disclosed species, a generic concept inclusive of the elected species will be identified by the Examiner for examination along with the elected species."

It is not understood what is meant by this statement. There is no provision in the statute or the rules of practice which allow for the identification of a "generic concept" for examination. It is fundamental that the claims presented by applicants must be examined. It is improper for the USPTO to refuse to examine the subject matter which the applicants regard as their invention unless the subject matter in a claim lacks unity of invention. See MPEP § 803.02. Here, no allegation has been made that any claim in the application lacks unity of invention.

In accordance with current USPTO species practice, the claims which are readable upon the elected species must be examined. Further, upon allowance of a claim or claims which are generic to the elected species, 37 C.F.R. § 1.141 provides that a reasonable number of species may be claimed in one application. Thus, claims 1, 7-8, 11-14, and 16-18, which are readable upon the elected species, must be examined in the present application.

In summary, reconsideration of the requirement for restriction, withdrawal thereof from the application and examination of all the claims in the application is respectfully requested. If the Examiner does not withdraw the restriction in its entirety, withdrawal of the Group III restriction and examination of claims 1-18 and 23-24 is respectfully requested.

Alternately, examination of claims 1-18 and 23 is requested.

Respectfully submitted,

Date: 12/30/2002

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